



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: **SEP 06 2002**

From: Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

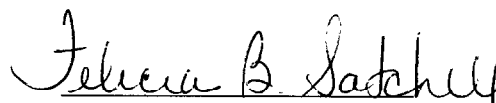
New Dietary Ingredient: L-Se-methylselenocysteine (SeMC)

Firm: PharmaSe, Inc.

Date Received by FDA: January 9, 2002

90-Day Date: April 9, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 as soon as possible since it is past the 90-day date. Thank you for your assistance.


Felicia B. Satchell

Attachments

95S-0316

RPT112

3416 Knoxville Ave.
Lubbock, TX 79413
Ph (806) 784-0104
Fax 806-687-0998
Email: sestech@door.net

Selenium Nutraceuticals for the Future

Julian E. Spallholz, PhD
Cell Ph. (806) 786-8349

3416 Knoxville Ave.
Lubbock, TX
79413
Ph (806) 784-0104
Fax 806-687-0998
Email: sestech@door.net

March 30, 2002

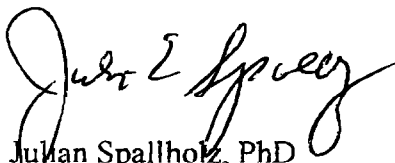
Felicia B. Satchell
Director
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food safety and Applied Nutrition
Food and Drug Administration
Washington, DC

Dear Ms. Satchell:

Thank you for your letter of March 25th advising me of your recommendations on the labeling of nutritional supplements containing 200 ug Se as Se-methylselenocysteine (SeMC). I have conveyed your message to the future retailer of these supplements and we will adhere to your directive. Thank you for your time in reviewing all the information we provided.

Thank you again.

Sincerely,



Julian Spallholz, PhD
President and CEO



March 25, 2002

Julian Spallholz, Ph.D.
President and CEO
PharmaSe, Inc.
3416 Knoxville Avenue
Lubbock, Texas 79413

Dear Dr. Spallholz:

This is in response to your letter to the Food and Drug Administration (FDA) dated December 21, 2001, making a submission for a new dietary ingredient premarket notification pursuant to 21 U.S.C. 350b(a)(2). Your notification concerns the new dietary ingredient called "L-Se-methylselenocysteine (SeMC)" that you want to market for adults in dietary supplements (tablet, capsule or gelcap), containing either 100 mcg of selenium (Se) to be taken up to twice a day or 200 mcg of Se to be taken once a day.

In follow up, you sent FDA a facsimile on March 20, 2002, confirming that SeMC is in the "L" isomer form of the selenoamino acid Se-methylselenocysteine, SeMC is synthetically produced by another company, and PharmaSe, Inc. would serve as the distributor of SeMC in the United States. This facsimile will be included as part of your notification filed by FDA on January 9, 2002.

On March 22, 2002, you sent us another facsimile that contained proprietary information about the tentative use of SeMC as an ingredient of an existing commercial dietary supplement product manufactured by another company. We do not consider this information to be part of your notification and did not consider this data in our assessment, because it does not specifically pertain to a SeMC-containing dietary supplement that you as the distributor and submitter of the new dietary ingredient notification intend to market.

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or

unless you have evidence indicating otherwise, it would be appropriate to exclude persons with renal problems from the potential population users of a SeMC dietary supplement when the recommended intake would provide 200 mcg of Se/day, unless a qualified health care provider advises its use.

Further, your notification does not include any information on the use of supplementation at the level of 200 mcg Se/day by pregnant and lactating women. These women represent a particularly vulnerable subgroup due to the dependence of the developing fetus and breastfed infant on maternal dietary intake and stores to meet their nutritional needs. There is some information in the scientific literature that indicates that Se supplementation of the lactating women can affect the Se concentration of their breast milk. In a study conducted by Trafikowska, *et. al.* (1996)⁷, lactating women received a Se-enriched brewer's yeast supplement for 1 month which significantly increased the level of Se in their breast milk.

Your notification does not address how Se intakes by pregnant and lactating women that approach or exceed the UL level may affect the fetus or breastfed infant. As a result, unless you have evidence indicating otherwise, it would be prudent to also exclude these subgroups from the potential population of users of a SeMC dietary supplement when the recommended intake would provide 200 mcg of Se/day, unless a qualified health care provider advises its use.

You also informed us that SeMC is synthetically produced. Because potentially deleterious impurities in processing may impact on the safety of this dietary ingredient, the manufacturer of SeMC should take appropriate measures to ensure that it is analytically pure and stable within normal storage conditions and does not degrade into a variety of chemicals.

In conclusion, the labeling of any SeMC dietary supplement, when recommended intake would provide 200 mcg Se/day as indicated in your notification, should clearly indicate that it is intended for use by adults only. FDA also encourages you to identify any subgroup(s) of consumers who might be placed at risk if they took a SeMC dietary supplement that provided 200 mcg Se/day and advise them to first consult a qualified health care provider before consuming it. To deter excessive intake of Se where selenosis or Se toxicity may occur, it would be helpful to advise all consumers not to exceed the recommended daily dose of SeMC.

Your notification will be kept confidential for 90 days from the date of its receipt. After, April 9, 2002, your notification will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public.

⁷ U Trafikowska, *et. al.*: Selenium supply and glutathione peroxidase activity in breastfed Polish infants, *Acta Paediatr*, 1996 Oct; 85(10):1143-5.

Selenium Nutraceuticals for the Future

Julian E. Spallholz, PhD
Cell Ph. (806) 786-8349

3416 Knoxville Ave.
Lubbock, TX
79413
Ph (806) 784-0104
Fax 806-687-0998
Email: sestech@deor.net

To: Rhonda R. Kane, MS RD
Office of Nutritional Products, Labeling
And Dietary Supplements
Food and Drug Administration
Washington, DC, 20204

301-436-2639

From: Julian Spallholz
PharmaSe, Inc



Re: Your Call of 3/15/02

Attached is analytical information on Se-methylselenocysteine (SeMC) from
and an HPLC analysis done by us. The amino acid is of the L
isomeric configuration as noted on the supporting documentation.

I am unable to provide information on supplement composition for as I told you in our conversation on Friday, PharmaSe, Inc have agreed to a manufacturing and marketing agreement with a pharmaceutical company for SeMC. I have contacted the company by email and told them of your request. They may need a few days to respond and I hope that they will engage you in direct communication. Thank you for understanding that I cannot speak for them. I will respond again by the end of the week at the latest with some additional information.

Thank you very much.

10 pages total.
SeMC synthesis Attached.

N.V.

Client code: PHAR BTW/TVA/VAT nr. client: none

PharmSe, Inc.

Prof. Julian Spallholz

3416 Knoxville Ave

Lubbock

TX 79413

USA

your PO #

sample

Certificate of analysis

31 jan 2000

Prod. nr.: 100.320

Batch nr.: sample1

PRODUCT NAME: **Se-Methylseleno-L-cysteine**

appearance: white crystalline powder

IR:

melting point: 167 - 170°C (decomposition)

TLC: 1 spot

particle size:

others: Assay: 95.6% (titration)

Comment:

Date: Wed, May 24, 2000 3:56 PM

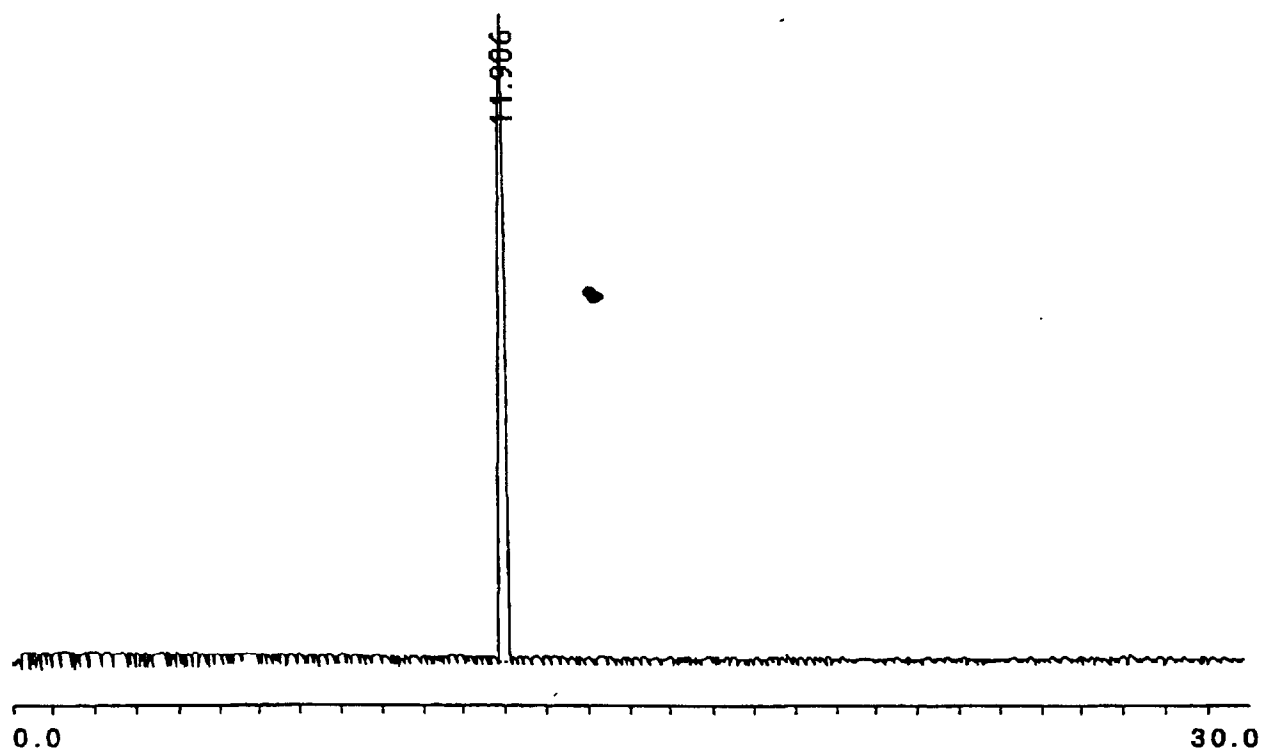
Data: No data saved

Method: peptide 1gradient

Sampling Int: 0.1 Seconds

Data:

SeMC

HPLC of Se-methylselenocysteine.

Analysis: Channel A

Peak No.	Time	Type	Height(μ V)	Area(μ V-sec)	Area%
1	11.986	N	5219	29277	100.000
Total Area				29277	100.000

**Redacted pages 4 – 10 from the March 20, 2002 facsimile
as they contained confidential commercial information**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

February 14, 2002

Julian Spallholz, Ph.D.
President and CEO
PharmaSe, Inc.
3416 Knoxville Avenue
Lubbock, Texas 79413

Dear Dr. Spallholz:

This is to inform you that the notification, dated December 21, 2001, you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by this office of the Food and Drug Administration (FDA) on January 9, 2002. Your notification concerns the new dietary ingredient called "Se-methylselenocysteine (SeMC)," and states that you want to market for adults only one or more SeMC dietary supplements containing either 100 mcg of selenium (Se) to be taken up to twice a day or 200 mcg of Se to be taken once a day.

This notification represents a resubmission of two earlier notifications you sent FDA in May and October 2001. On July 27, 2001, we responded in a letter to your May notification stating that it provided an inadequate basis for concluding that up to 200 mcg of additional Se provided in a SeMC dietary supplement was reasonably expected to be safe for adults who already consume a high amount of Se in their diets.

The subsequent notification you sent us in October 2001 for the same intake of Se in a SeMC dietary supplement was incomplete and did not meet the minimum requirements of 21 CFR §190.6. Therefore, our November 28, 2001 letter informed you that FDA would not review the evidence of safety information included in that notification until the noted deficiency was corrected. We further advised you that because your notification did not comply with regulatory requirements, you could not legally market your proposed SeMC dietary supplement. You elected to send us the current new and complete notification in an effort to meet the minimum requirements of 21 CFR §190.6.

In accordance with 21 C.F.R §190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date (i.e., after March 25, 2002), you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains 100 mcg of SeMC for use twice a day or that contains 200 mcg SeMC for use once a day.

You may legally market SeMC as described in the notification any time after March 25, 2002, if FDA does not otherwise notify you in writing by that date. However, the lack of an FDA response does not constitute a finding by the agency that a SeMC dietary supplement supplying Se at the levels described in your notification is safe or that the product is not adulterated under 21 U.S.C. 342. Further, FDA is not precluded from taking action in the future against any dietary supplement containing SeMC if it is found to be unsafe, adulterated or misbranded.

As another procedural matter, your notification will be kept confidential for 90 days after the filing date. Therefore, after April 9, 2002, the notification will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information that is in the notification will not be disclosed to the public.

Prior to April 9, 2002, you may wish to identify in writing specifically what information you believe is proprietary in your current notification for FDA's consideration. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

For your future reference, if you intend to make any claims about the benefits of taking a SeMC dietary supplement in the product's labeling or advertising, such statements must comply with applicable FDA and Federal Trade Commission (FTC) regulatory requirements, respectively. Please be aware that if a product is represented as a drug, defined under 21 U.S.C. 321(g)(1)(B) as an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, it would be subject to regulation under the drug provisions of the Federal Food, Drug and Cosmetic Act.

The FDA Internet site <http://www.cfsan.fda.gov/~dms/ds-labl.html#structure> provides details on the types of claims that are allowed for dietary supplements, including structure/function, health and nutrient content claims. Federal regulations at 21 CFR §101.36 address the general labeling requirements of all dietary supplements whether or not claims are made.

For claims that are allowed under 21 U.S.C. 343(r)(6) (e.g., those related to the structure or function of the human body or one's general well-being), a dietary supplement's labeling must include a specific disclaimer. In addition, the product's manufacturer or distributor must notify FDA in writing about a structure/function claim no later than 30 days post marketing. Federal regulations at 21 CFR §101.93 specify the notification requirements for such claims. These notification requirements are separate from the new dietary ingredient premarket notification program.

Page 3 - Dr. Spallholz

FTC Internet site <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm> provides details on Federal requirements concerning the advertising of dietary supplements. All dietary supplement claims made in both product labeling and advertising must be substantiated with scientific evidence, be truthful, and not be misleading.

Please contact me at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Rhonda R. Kane". The signature is fluid and cursive, with the first name "Rhonda" being more prominent than the last name "Kane".

Rhonda R. Kane, M.S., R.D.
Consumer Safety Officer
Dietary Supplements Team
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Page 4 - Dr. Spallholz

cc:

HFA-224 (yellow box copy)

HFS-800 (Reading File)

HFS-805 (Coody)

HFS-810 (Foret)

HFS-811 (Moore)

HFS-820 (Satchell)

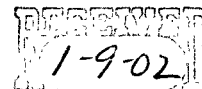
HFS-821 (Kane—3 copies, Chang, McCollum, Strauss)

R/D:HFS-821:RKane:301-436-1803:2/7/02

Revised: HFS-820 (Satchell):2/12/02

DOC: saved on “p” drive via:

DSLRLdata/Dietary SupplementTeam/NDI/Confidential/SeMC/78999 SeMC Ack Letter for
Jan 2002 Submission



Selenium Nutraceuticals for the Future

Julian E. Spallholz, PhD
Cell Ph. (806) 786-8349

3416 Knoxville Ave.
Lubbock, TX
79413
Ph/fax (806) 784-0104
Email: sestech@door.net

12/21/2001

Felicia B. Satchell
Director
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, RM 4D008
College Park, MD
20740

Dear Ms. Satchell:

PharmaSe, Inc requests the consent of the FDA to introduce into the nutritional supplement marketplace Se-methylselenocysteine (SeMC), a naturally occurring selenoamino acid extensively made by plants of the Allium family to include garlic, broccoli, onions, ramps, etc. This selenoamino acid is also found in yeasts and Se-yeast supplements. PharmaSe, Inc requests permission under the 1994 DSHEA regulations to market tablets and /or capsules to adults up to a maximum of 200 ug Se as Se-methylselenocysteine. Your permission to allow Se-methylselenocysteine to be sold up to 200 ug Se/day would be comparable to the commonly marketed 200 ug Se/day of selenomethionine, or Se-yeast and the 250 ug Se/day of sodium selenite. Two hundred ug Se/day supplements have been offered to the adult public as a health benefit for more than twenty years with, to our knowledge, no reported adverse effects of any kind. On the contrary, a 200 ug Se/day supplement is reported in the literature to have multiple beneficial health effects, Rayman, (The Lancet, 2000). A supplemental dose of 200 ug Se/day as selenomethionine is presently being given to tens of thousands of American men in the PRECISE (PREvention of Cancer by Intervention with SElenium) Trial (of selenium and Vitamin E supplements) funded by the National Cancer Institute to retest the 1996 findings of Clark et al, (JAMA) that supplemental selenium protected against prostate cancer. Recent experiments by Hawkes et al, (BTER, 2001) with elderly people showed that several immune system parameters were improved by supplementation with 200 ug Se/day.

We are aware that selenium has the potential to be toxic to humans and yet there are no reports of 200 ug Se/day to elicit any adverse effects in thousands of human years of consumption of selenium supplements by the general public or in controlled human experimentation. Additionally, "all selenium compounds" on an equivalent selenium basis is not equally toxic. In animal experimentation inorganic selenium, i.e. selenite, is much more toxic than selenomethionine. This fact has been demonstrated over and over again in cell culture, in organ culture and in many animal species. We have examined and directly compared the toxicity of

of diet and find no statistical differences in the physiological parameters measured. We have also shown, as have others, that selenomethionine accumulates in tissues as selenomethionine replaces methionine, an essential amino acid, in the primary protein structure. Se-methylselenocysteine in contrast, is a non-protein amino acid and does not accumulate in protein and tissues, as does selenomethionine. Therefore toxicity of Se-methylselenocysteine supplementation from accumulation in body tissues should not be of any concern. Tissue levels of selenium from Se-methylselenocysteine only reflect ingestion and selenium levels plateau while tissue levels of selenium from selenomethionine continually and progressively accumulates and exceeds what otherwise would be lower dietary selenium plateau levels.

Attachments (3 copies each) for your review to our request include: 1) a list of companies presently marketing selenium and the stated amount of selenium per tablet or capsule /day. Sixteen of the 19 companies surveyed offer 200 ug Se/day supplements. 2) A compilation of the Essentiality of Selenium for Humans showing the selenium intake as ug Se/day and for an idealized 70 kg person, the selenium source, either diet or diet and supplement and the effect noted in the literature. The Maximum Safe Limit (NOAEL) is 819 ug Se/day or 15 ug Se/kg body weight. This amount is 3X higher for example than people presently enrolled in the NCI PRECISE trial. Also attached is a compilation of Toxicity of Selenium in Humans. In all but one case, known to me personally, the form of selenium is not reported. If the selenium was inorganic in all cases then toxicity were it to be reported for selenomethionine or Se-methylselenocysteine would all carry higher values by at least a factor of magnitude. Thus individual LOAEL would not be 900 but 9000 ug Se/day were toxicity responsible from organic dietary supplements. 3) Lastly, attached is original literature demonstrating the natural presences of Se-methylselenocysteine in plant foods, the long standing use of selenomethionine and Se-yeast as dietary supplements at 200 ug Se/day, the absence of any reported adverse effects of 200 ug Se/day in the formal human studies conducted and the reported health benefits of selenium supplementation at 200 ug Se/day.

In summary, we at PharmaSe, Inc believe that the totality of evidence demonstrates that 200 ug Se/day of Se-methylselenocysteine as a dietary supplement will not accumulate in body tissues nor will it be toxic at this level of dietary supplementation. We request permission to market to adult humans Se-methylselenocysteine at 200 ug Se/day as tablets, capsules or gel caps to read as follows:

Directions for Use: Take one tablet (capsule, gel cap) daily as a dietary selenium supplement. Each tablet (capsule, gel cap) contains 200 ug of selenium as Se-methylselenocysteine. *

and/or

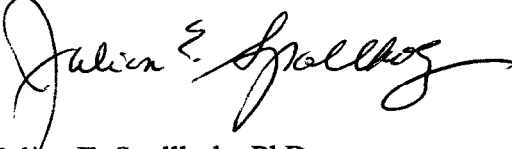
Directions for Use: Take two tablets (capsules, gel caps) daily as a dietary selenium supplement. Each tablet (capsule, gel cap) contains 100 ug of selenium as Se-methylselenocysteine. *

* Se-methylselenocysteine is a naturally occurring selenium containing amino acid found in plant foods of the Allium family.

The following will appear on the label: This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Thank you again for your time in reviewing our request. I shall be pleased to respond to any questions you might have.

Sincerely,

A handwritten signature in black ink, reading "Julian E. Spallholz". The signature is fluid and cursive, with the first name "Julian" being the most prominent part.

Julian E. Spallholz, PhD
President and CEO

Enclosures: (3 each)

List of Selenium Supplements in Commerce
Table of Selenium Essentiality in Humans
Table of Selenium Toxicity in Humans
Reprints of Reviews and Original Research Reports

Companies that Retail Selenium Supplements

1. Country Life
Hauppauge NY 11788
200 ug Se as yeast selenomethionine
www.country-life.com
2. Twin Labs
Ronkonkoma, NY 11779
250 ug Se as sodium selenite
www.veromaxxx.com/TwinLab/
3. Solaray Made They are a label for Nutraceutical Corp
200 ug Se as yeast selenomethionine
4. Natural Factors
3686 Bonneville Place,
Burnaby BC
Canada V3N 4T6
Tel: (604) 415-4187 Fax: (604) 420-0743
100 ug Se as yeast selenomethionine
www.naturalfactors.com
5. Now Foods
Bloomington IL 60108
www.Nowfoods.com
200 ug Se as selenomethionine advertised as yeast free do not take more than one capsule daily
sales@nowfoods.com
internationalsales@nowfoods.com
888-NOW-FOODS
6. BlueBonnet
Sugarland, TX 77478
200 ug Se as selenomethionine

7. Solgar
500 Willow Tree Road
Leonia, N.J. 07605
200 ug Se as selenomethionine they also sell a 200ug yeast product (from Cypress) and a
150 ug Se as selenomethionine plus vitamin E (500IU)
www.solgar.com
1-877-765-4274 (for Consumers)
1-800-645-2246 (for Retail Stores)
8. Natures Plus.com
Natural Organics Headquarters
548 Broadhollow Rd.
Melville, NY 11747-3708
Email - Info@naturesplus.com
Telephone - (631) 293-0030
Fax - (631) 293-0349
<http://www.naturesplus.com>
200 ug Se as selenomethionine yeast plus 100 IU Vit E
9. Jarrow Formulas™
1824 S. Robertson Blvd
Los Angeles, CA 90035
(800)726-0886
www.jarrow.com
200 Se as ug selenomethionine
10. Nutraceutical Corp.
1400 Kearns Blvd., Second Floor
Park City, UT 84060. Call 800.669.8877
200 ug Se as selenomethionine yeast they also have a 100 ug yeast free capsule
www.nutraceutical.com
their brands are Solaray, KAL, NaturalMax, VegLife, Premier One, Solar Green and
Natural Sport
11. Whole Foods Inc.
601 N. Lamar
Austin, TX 78703
200 ug Se as selenomethionine
512-477-5566
www.wholefoods.com

12. New Chapter
22 High Street
Brattleboro, VT 05301
(800) 543-7279 Fax: (800) 470-0247 info@new-chapter.com
200 ug Se as selenomethionine yeast
www.Newchapter.com
800-543-7279
13. Wild Oats
3375 Mitchell Lane
Boulder, CO 80301
www.wildoats.com
800-494-WILD
200 ug Se as selenomethionine yeast
14. Natures Life
7180 Lampson Ave.
Garden Grove, CA 92841
<http://www.natlife.com/>
(714) 379-6500 FAX (714) 379-6501
200 ug Se as selenomethionine yeast
15. Megafood
P.O. Box 325
Derry, NH 03038
www.megafood.com
800-848-2542 FAX 603-432-2111
100 ug Se as foodstate ?? selenium
16. Walgreens
200 Wilmot Road
Deerfield, IL 60015
(847) 914-2500
<http://www.walgreens.com>
200 ug Se as selenomethionine yeast made by Nutrition 21

17. Nature Made
Mission Hills, CA 91346
800-276-2878
www.naturemade.com
200 ug Se as selenomethionine yeast
18. Sundown
6111 Broken Sound Pkwy. N.W.
Boca Raton, FL 33487
<http://www.rexallsundown.com>
(800) 327-0908
200 ug Se as selenomethionine yeast
19. Linear Health Products
Carson CA 90745
selenium

Essentiality of Selenium in Humans

<u>Se ug/day</u>	<u>ug Se/kg Body Weight</u>	<u>Chemical Form</u>	<u>Effect(s)</u>
<11	<0.20	Dietary	Keshan Disease Kashin-Beck Disease
16	0.31	Dietary	Minimum Dietary Requirement
41	0.67	Dietary	Adequate dietary Requirement
55	-----	Dietary	1989 US RDA for Women
55	-----		1999 US RDA for Women
73	-----		2000 a Calculated Required US RDA for Women (Rayman, The Lancet, 2000)
70	----	Dietary	1989 US RDA for Men
55	----		1999 US RDA for Men
80-165	----	Dietary	US Dietary Intake Range
100		Dietary	Glutathione Peroxidase Saturation of Platelets
300+	----	200 ug Se/day Supplements, Selenomethionine	Immune Enhancement, Cancer Reductions in Humans, NCI SELECT Trial
350	5	Diet and Supplements	RfD 70 kg Adult
400	-----	Diet and Supplements	Suggested Maximum Safe Limit
600	11	Diet and Supplements	Individual Maximum Safe Limit
724	----	Diet and Supplements	Level Identified as Safe in Adult Americans
819	15	Diet and Supplements	Maximum Safe Limit (NOAEL)

Toxicity of Selenium in Humans

<u>Se ug/day</u>		<u>ug Se/kg Body Weight</u>	<u>Chemical Form</u>	<u>Effect(s)</u>
900		17	Diet and Supplements	Low Level Toxicity (Individual LOAEL)
1000	-	----	Diet and Na ₂ SeO ₃ Supplement	Personally Known Intake Daily for Years with NOAEL
1,540		28	Diet and Supplements	Low Level Toxicity (Mean LOAEL)
1,600		30	Diet and Supplements	Adverse Effective Level
5,000		90	Diet and Supplements	Selenosis, Hair and Nail Loss
15,000		270	Diet and Supplements	Overt Selenosis

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